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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,935	08/21/2003	Ivan Lieberburg	9626-17	7376

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,935	LIEBERBURG, IVAN	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/20/2008 has been entered.

Status of the Claims

Claims 16-31 are cancelled. Therefore, claims 1-15 is currently pending examination for patentability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Elan Pharma (Zonisamide Approvable Labeling, Published 03/27/2000) in view of Iliopoulou et al. (Acute Pancreatitis Due to Captopril Treatment, Disgestive Diseases and Sciences, Vol. 49 No. 9, pp. 1882-1883, Published 09/2001) **is maintained**.

Applicant Claims

Applicant claims a method of improving safety, managing health, and ameliorating adverse side effects in a patient receiving zonisamide treatment for epileptic seizures by informing the patient that pancreatitis is a potential side effect and to seek immediate medical attention should the patient experience one or more symptoms associated with pancreatitis.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Elan Pharma teaches, "**Zonegran™ (zonisamide) is an antiseizure drug** chemically classified as a sulfonamide and unrelated to other antiseizure agents." (See page 1, Lines 3-4). "**Zonegran** is supplied for oral administration **as capsules** containing **100 mg zonisamide**." (See page 1, Lines 10-11). "Start with one Zonegran capsule each day (100 mg). Swallow the capsule whole." (See page 23, Line 4). "After a week or so, your doctor may increase your dose of Zonegran. This may occur more than once. It is done to get the best control for your seizures. Take only the number of Zonegran capsules you were told to take." (See page 23, Lines 6-8). Elan Pharma

further teaches, "The most **commonly observed adverse events associated with the use of Zonegran** in controlled clinical trials that were not seen at an equivalent frequency among placebo-treated patients were somnolence, **anorexia**, dizziness, headache, **nausea**, and agitation/irritability." (See page 14, Lines 14-17). "**Contact your doctor right away if**: … **you develop** signs of kidney stones (sudden back pain, **abdominal pain**, blood in your urine) …" (See page 24, Lines 5-9).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Elan Pharma does not teach informing the patient that pancreatitis is a potential side effect of zonisamide treatment. Iliopoulou et al. cure this deficiency.

Iliopoulou et al. teaches that there are **drugs** that **can cause acute pancreatitis**. (See page 1882, Column 1, Lines 30-31). "The most **frequently incriminated drugs** are **sulfonamide derivatives**, valproic acid …" (See page 1882, column 1, Line 31 and column 2, Lines 1-2).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Elan Pharma and Iliopoulou et al. One would have been motivated to do so because Elan Pharma teaches that zonisamide is a sulfonamide class of drug and Iliopoulou et al. teaches that this class of drugs are known frequently to cause acute pancreatitis. Therefore, if one wanted to inform a patient of all the adverse side effects

associated with zonisamide one would inform them of the potential for acute pancreatitis as this has been implicated in similar drugs of the sulfonamide class. Further because Elan Phrama teaches that one taking zonisamide should seek immediate medical attention in the case of sudden back pain or abdominal pain, which are also symptoms of pancreatitis, it would have been obvious that a patient would seek medical attention upon experiencing these symptoms and then a medical practitioner would perform the necessary tests to determine if pancreatits is the proper diagnosis. Therefore, the improvement of the information provided the patient to include pancreatitis would have been obvious to one of ordinary skill in the art in view of the teachings of Iliopoulou et al. For the foregoing reasons the instant methods would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicant Arguments

Applicant argues that it would not have been obvious to one of ordinary skill in the art to combine the teachings Elan Pharma with Iliopoulo et al. because a teaching of a class of drugs such as sulfonamide being associated with pancreatitis would not lead one of ordinary skill in the art to expect that each and every drug in the class of drugs would be associated with pancreatitis. Applicant's arguments have been fully considered and found not to be persuasive. The teachings of Elan Pharma already indicate that a patient is to be informed that should they experience abdominal pain they should immediately contact their doctor. Elan Pharma also teaches that nausea and anorexia are other side effects associated with taking zonisamide. In light of the

teachings of Iliopoulo et al. that the class of compounds sulfonamides, of which zonisamide is one of, are associated with pancreatitis it would have been obvious to one of ordinary skill in the art at the time of the instant invention to associate the symptoms already taught by Elan Pharma with the condition of pancreatitis and thereby inform a patient of the possibility of such a condition occurring during treatment. For the foregoing reasons the rejection of claims 1-15 under 35 U.S.C. 103(a) is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616